NATIONAL INSTITUTES OF HEALTH
NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES
NATIONAL KIDNEY DISEASE EDUCATION PROGRAM

STEERING COMMITTEE MEETING
HYATT REGENCY HOTEL
Crystal City, Virginia

EXECUTIVE SUMMARY
September 20-21, 2004

I. WELCOME

Thomas Hostetter, MD, Director of the National Kidney Disease Education Program (NKDEP) at the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) opened the meeting. He thanked all for participating and introduced Josie Briggs, MD, Director of the Division Kidney, Urologic and Hematologic Diseases at NIDDK. Dr. Briggs said she views NKDEP as a challenging and important program. There is a need for an education program to change the care of those with or at risk of kidney disease. She then outlined the purpose of the meeting stressing that NKDEP is to be congratulated for its accomplishments in the last three years but the magnitude of the problem continues unabated. The program depends upon the organizations represented on this Steering Committee to spread the message. This is an example of a federal government partnership with outside organizations. Federal leadership drives the effort. Dr. Briggs said the committee would hear of the important strides made by NKDEP and is looking for their input on future directions.

II. BACKGROUND

Elisa Gladstone, MPH, Associate Director of NKDEP, updated attendees on program activities to date. She began with the social marketing campaign, "You have the power to prevent kidney disease." The primary audiences are African Americans at risk for kidney disease and primary care physicians (PCPs) who diagnose and treat kidney disease. New materials in this effort have been available since June and include a new cover photo of an African-American physician on one brochure with an insert for patients who have diabetes or high blood pressure. There is also a multi media component in the campaign with a four-minute video on the risk factors for kidney disease, the importance of testing and treatment options. This has been used in churches, doctors' waiting rooms and screenings. Other efforts to spread the message include the following:

- Radio Public Service Announcements (PSAs)
  - -Designed to reach African Americans
  - -Available in 30 or 60 second versions
  - -Message is to know risks for kidney disease and to continue to take medications
  - -Radio media tour with medical spokespersons including Drs. Tom Hostetter, Janice Lea and Donald Wesson

● Toll free number

● Redesigned website
  -In 4 months since the launch had 285,000 "hits" per month

● "Help Your Family Prevent Kidney Failure" dialysis materials
  -Encourages patients to educate family members on risks as well as importance of being tested
  -Materials for waiting rooms and for dialysis center staff
  -Includes a brochure, poster and staff button

● Kidney Disease Reference Card (formerly known as the PCP Targets)
  -This is a one-page distillation of screening, prevention, and treatment targets
  -Two-sided laminated card

● Rationale for Reporting Estimated GFR fact sheet
  -Gives 7 reasons to use prediction equations

● Suggestions for Laboratories fact sheet
  -Recommendations for laboratories to report GFR values below 60 mL/min/1.73 m^2

● Working on Understanding GFR for Patients fact sheet
  -Answers 5 questions on GFR
  -Available October 2004

Distribution of these materials is critical. Ms. Gladstone said one avenue to accomplish distribution is working partners. Industry partners, for example, have been active in distributing materials through their sales forces. She reminded Steering Committee members that NKDEP materials are copy-right free and encouraged participants to help NKDEP distribute materials. Co-branding opportunities are available.

III. PRESENTATIONS
Charlene Melcher, PhD
Director, Research and Account Planning
Equals Three Communications

Dr. Melcher works with the Evaluation Working Group for NKDEP and she updated attendees on current evaluation efforts utilizing NIH set-aside funding.

The key components of the NKDEP pilot site evaluation are the process evaluation and the baseline and follow-up survey of NKDEP target audiences. The goal of the process evaluation was to assess the program and its materials. Dr. Melcher explained how the process evaluation collected data on all NKDEP activities, events, materials distribution and media outreach, including a content analysis of the quantity and quality of media coverage. She also presented findings of the follow-up survey to assess knowledge, attitudes and behaviors related to kidney disease among NKDEP targets. Findings are as follows:

- Coalition members conducted about 340 unique activities or events (i.e. screenings, health fairs, golf tournaments and other activities).
- Most activities targeted African-American adults.
- Over 35, 000 copies of the NKDEP consumer brochures were distributed.
  -Includes materials distributed by both coalition members and the national office
- Media coverage in all sites generated 15 million impressions.
- The quantity and quality of media coverage improved during the pilot site program and kidney disease was a more central feature of discussion.

Over 2,000 randomly selected African-American adults participated in a follow-up survey in the pilot sites and a three-city composite control site. The sample had a somewhat higher incidence of diabetes, hypertension and kidney disease than that reported nationally. In terms of demographics, most respondents were female (71%), reported household income under $40,000 per year (43%), and had a high school degree or less (32%) or some college (35%) education. The key findings were as follows:

- Around forty percent said they had heard that diabetes causes kidney disease and almost sixty percent said they had heard hypertension does. However, there is still a lack of awareness among this population.
- Over forty-five percent said they did not know what causes CKD.
- Over thirty-five percent said they did not know what a doctor might tell them to help prevent CKD.
- About a third said difficulty urinating, general pain or frequent urination would let someone know they had CKD.

Over 780 physicians, nurse practitioners and physicians assistants participated in the follow-up survey of primary care providers in Atlanta, Baltimore and Cleveland. In terms of demographics, 71% were physicians, 50% had been in practice for five years or less, and about a third (35%) said that 26-50% of their patients were African American. Some key findings were:

- When asked to indicate when they would diagnose CKD based on a hypothetical patient scenario, about 65% gave a creatinine level within a diagnosis range preferred by NKDEP, about 75% gave an acceptable albumin/creatinine ratio diagnosis point, about 35% gave an acceptable proteinuria diagnosis point, and about 20% an acceptable estimated GFR diagnosis point.
- When asked what topics they discussed with those at risk for CKD, nearly all said they discussed controlling hypertension and diabetes, about 90% said the severity/complications of CKD and about 75% the importance of exercise.
- When asked what treatment options were regarded as most important, providers rated lowering blood pressure, achieving tighter glycemic control and quitting smoking the more favorable.

The findings suggest that providers still need more education on CKD diagnosis, treatment and prevention.

Data from the baseline and follow-up survey will be made available once the findings have been submitted for publication. NKDEP welcomes suggestions on evaluating the program or on doing more targeted evaluations in the future.

Dick Goldman, MD
Chair, Quality and Accountability Committee
Renal Physicians Association (RPA)

The RPA and NKDEP developed a Consult Letter Template. The letter is intended to:

- Clarify CKD stage-specific tasks and delineate who will accomplish the tasks
- Facilitate communication between the nephrologists and the primary care providers
- Educate PCPs about GFR, CKD staging and stage-specific tasks
- Improve implementation of guidelines

The Letter is Web-based and has drop-down menus for nephrologists to choose the appropriate answers for each case. The letter highlights areas of care such as diabetes, estimated glomerular filtration rate (GFR) and recommendations for the CKD care of the patient. Patient-specific information initially entered by the nephrologist automatically appears throughout the letter as appropriate. After the key elements have been selected, a letter is generated. The letter can be printed and mailed to the PCP, saved onto the hard drive or sent electronically. Patient information entered onto the template is not stored or saved on the Web site. The letter will ease the burden on practitioners and hopefully improve outcomes of those with CKD. It contains clear choices regarding the division of responsibility between the nephrologist and the PCP.

A promotion plan for this Consult Letter Template is being developed. After tracking usage, the letter will be converted for PDA use so that it can be sent after a hospital consultation or before a patient is discharged from the hospital. Additional templates will be considered in the future, e.g. follow-up visits, full history and physical consults and PCP-specific letters. RPA also developed 5 patient-specific tools and 19 physician-specific tools that are being piloted. Post the pilot stage, these tools will be offered to NKDEP.

Feedback from those who received the letter is being studied. The results are not yet available. The letter is on the Web site and was shown at meetings of the RPA and the American Society of Pediatric Nephrology. The National Kidney Foundation (NKF) is adapting the letter to a tool kit they are developing.

Laboratory Working Group Report
John Eckfeldt, MD, PhD
Professor, University of Minnesota

The Laboratory Working Group is composed of people from various backgrounds including chemists, clinical pathologists, and manufacturers. The Working Group also includes representatives from the Food and Drug Administration (FDA), the Centers for

Disease Control (CDC), professional organizations such as the College of American Pathologists (CAP) and large reference laboratories. Dr. John Eckfeldt, Chair of the Laboratory Working Group, presented an overview of the Working Group—its mission and activities.

The Laboratory Working Group was charged with developing programs to standardize and improve serum creatinine measurements to allow more accurate estimation of GFR. The audiences are providers, in vitro diagnostic (IVD) manufacturers and clinical laboratories. The problem is many clinical serum creatinine methods have systematic biases of up to 20% from the true serum creatinine value in the range important for GFR estimation. Any bias in the serum creatinine measurement creates a systematic bias in the GFR estimation which is roughly equal in magnitude (when expressed as percentage) but in the opposite direction of the serum creatinine bias. For example, a lab which systematically reports serum creatinines that are 15% high would systematically report estimated GFR that are 15% too low.

NKDEP currently recommends clinical reporting of the estimated GFR using the MDRD equation when the GFR is estimated to be less than 60 mL/min/1.73 m^2—a range which may be expanded in the future. The MDRD equation is thought to be more accurate at lower GFRs. Furthermore, serum creatinine percent bias also appears to decrease as the serum creatinine rises and the GFR falls.

Dr. Eckfeldt reported progress made in the effort to standardize measurement and report estimated GFR. The Working Group has proceeded in a manner similar to that of the National Cholesterol Education Program (NCEP). They are working to standardize serum creatinine measurements across clinical laboratories. A new National Institute of Standards and Technology (NIST) frozen serum-based reference material (calibrator) is planned for Fall 2004. A pilot test of a new "accuracy-based" proficiency method has been completed and it will be offered this fall by the College of American Pathologists. The results will help in the effort to keep manufacturers' methods calibrated to true values. Working Group members presented at the American Association for Clinical Chemistry in July of this year and a manuscript on the current "state-of-the-art" of clinical creatinine measurements is being completed.

Goals for the next year for the Laboratory Working Group include the following:

- Assure that the College of American Pathologists (CAP) Creatinine Linearity Survey is introduced in the Fall 2004
- Publish the manuscript on the "state-of-the-art" of clinical creatinine measurements in *Clinical Chemistry*
- Assure that the NIST frozen serum-based reference material (calibrator) is introduced in the Fall of 2004
- Reduce total error of clinical serum creatinine measurements to less than $^{+}$/- 15% in the critical range of 0.5 to 4.0 mg/dL by mid-2005 and possibly lower ($^{+}$/- 10%) in future years.

Quality Indicators Working Group Report
William McClellan, MD, MPH
Medical Director
Georgia Medical Care Foundation

Dr. McClellan gave a report from the NKDEP Quality Indicators Working Group. The Working Group has concentrated recent efforts on the Centers for Medicare and Medicaid Services' (CMS) Quality Improvement (QI) infrastructure to improve CKD in those patients with cardiovascular disease (CVD). They have been involved in a pilot program to see if there was a Quality Improvement opportunity in these observations. CMS covers dialysis patients and their QI activities have improved care in end stage renal disease (ESRD) patients. In CKD there is a similar infrastructure for QI with Quality Improvement Organizations (QIO)s in each state.

Medicare does hospital-based chronic disease surveillance. Analyses of the surveillance results have been published in the Journal of the American Medical Association (JAMA). Hospitals send data to CMS. That information goes to the state quality improvement organization and is used by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). QI data on heart failure and acute myocardial infarction (AMI) is used by CMS to assess hospital care and is also included in hospital accreditation surveillance. The goal now, Dr. McClellan said, is to get CKD on the list, too.

The pilot study focused on Medicare populations with cardiovascular disease (CVD) because the national data show the Medicare beneficiary population has a high incidence of CKD. Most with AMI and heart failure who are admitted with these two diagnoses also have an indicator for CKD. This suggests that QI activities targeted at that population would be appropriate. Last year, Dr. McClellan and his colleagues asked NKDEP to work with them. They developed QI indicators to drive this pilot study. The QI indicators were selected primarily from the National Kidney Foundation's Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines including using estimated GFR computed via the MDRD equation. They also referred to the JNC VII and the American Dietetic Association (ADA) guidelines. QI indicators also included the identification of CKD, use of an angiotensin-converting enzyme inhibitor (ACE)/ angiotensin receptor blocker (ARB), dietary counseling with protein prescription and detection/management of anemia.

Pilot planning began in June 02 on the need for a CVD/CKD initiative. The Steering Committee endorsed it with a recommendation to CMS for a pilot in June 03. The Georgia Medical Care Foundation (GMCF) proposed and got acceptance for a pilot study in September 03. They started working with a national faculty, recruited physicians and their hospitals and engaged them in an assessment of care at their facilities.

Dr. McClellan provided details on the actual workings of the pilot and then reviewed study results. The pilot sites were: two rural hospitals, three regional centers and two academic centers. They all collaborated and shared experiences throughout the study, thereby learning from each other. Five of the seven implemented GFR reporting while

two are in the process of implementing it. ACE/ARB use was addressed in four out of the seven and nutrition was addressed in five out of the seven. The pilot hospitals re-engineered the process of reporting GFR and getting it into the chart prior to discharge. At the beginning of the study only five percent of the charts were labeled CKD; then fifty percent were labeled CKD based on GFR then it dropped to thirty percent and has stabilized at that rate. A substantial number of patients with CKD were previously not identified. Hypertension patients were previously sent home without being on an ACE or ARB. The study also found that the worse the renal failure or CVD, the less likely the patient was to go home on the appropriate medication.

This pilot will now be taken to the academic hospital centers. This is the CVD/CKD Academic Quality Improvement Collaborative also being done in partnership with NKDEP. The GMCF study proposal was approved and funded in September 04 with an estimated completion date of June 06.

Eric Simon, MD
Associate Professor of Medicine, Tulane University Medical Center
American Heart Association
Council on the Kidney

Dr. Simon said the Council on the Kidney is one of thirteen councils. The AHA is interested in kidney disease due to the large burden of CVD in the ESRD population as well as in those who are pre-ESRD. AHA is being propelled by the new data showing that kidney disease, even when mild, is a risk factor for CVD. The Clinical Cardiology and the Kidney Councils plans to sponsor a conference on this topic. There is interest in this topic from the top of the organization. Other activities of the Council on the Kidney include:

- Position Papers
  - -One on CKD as a risk factor for CVD
  - -One on the diagnosis of CKD via proteinuria, GFR, i.e. synopsis of the KDOQI guidelines done with the NKF and management of CVD risk factors
- Co-branding education materials

After a conference call with NKDEP, AHA sent a proposal suggesting they do even more than NKDEP had asked. There are opportunities for involvement. They are particularly interested in co-branding NKDEP and AHA materials with each other's logos on the materials.

Dr. Simon welcomed suggestions on ways to work with AHA, especially on co-branding. The professional side of AHA has 100,000 professional members so getting their support and having them spread the NKDEP messages would be ideal.

Dr. Hostetter told participants that two articles using the MDRD equation to compute GFR in CVD patients are coming out in the New England Journal of Medicine. These

articles and the accompanying editorial (by Dr. Hostetter) emphasize the importance of moderate kidney failure as a risk factor for cardiovascular disease.

Steering Committee Meeting
September 21, 2004

Dr. Thomas Hostetter opened the second session with an update of the latest ESRD figures. The number developing ESRD each year continues to rise with more than 100,000 cases diagnosed in 2002. However, the rise appears to be attenuating somewhat. The numbers are still large, however, with 400,000 living with kidney failure today. There is definitely a need for an educational program in kidney disease: it is a large public health problem, there is something that can be done about it and current therapy is not effective. Many of those who have it don't know they have it. In the most recent National Health and Nutrition Examination Survey (NHANES) data among those with a GFR less than 60, only 18% of men had been told they had CKD and only 3% of women had been told. This finding relates to laboratory reporting and poor recognition among women. It is critical that laboratories report GFR with the gender term inserted in the MDRD equation. Level of awareness of the disease is modest.

Screening for Proteinuria in U.S. Adults-A Cost-effectiveness Analysis
L. Ebony Boulware, MD, MPH
Johns Hopkins Medical Institutions

Dr. Boulware presented findings of a cost-effectiveness analysis using a Markov decision analytic model comparing a strategy of annual screening for CKD with no screening (usual care) for proteinuria at age 50 years followed by treatment with an angiotensin-converting enzyme (ACE) inhibitor or an angiotensin II-receptor blocker (ARB). Study investigators hypothesized that screening for early identification of CKD could improve public health but could also lead to unnecessary harms and excess costs. The main outcome measure was cost per quality-adjusted life-year (QALY).

Dr. Boulware presented the study findings which were as follows:

- For those with neither hypertension nor diabetes, the cost effectiveness ratio for screening vs. no screening beginning at age 50 was unfavorable.
- Screening persons with neither hypertension nor diabetes beginning at age 60 years resulted in a better ratio ($53,372 per QALY, incremental cost of $476 and a gain of 0.03 QALY per person).

Cost effectiveness was mediated by both CKD progression and death prevention benefits of ACE inhibitor and ARB therapy.

Investigators concluded that early detection of urine protein as a means of finding, treating and thereby slowing progression of CKD and decreasing mortality is not cost-effective unless selectively directed toward high-risk groups, i.e. older persons and those with hypertension, or if done at infrequent intervals of about 10 years. Proteinuria was

selected as a marker of CKD since it is a more powerful indicator than serum creatinine alone, Dr. Boulware said.

One meeting participant commented that the study provided good information but was tilted toward the negative. The study carries the message, "Don't screen," whereas the findings show the importance of screening in certain populations such as the elderly, diabetics and hypertensives. Dr. Boulware responded that she and her colleagues decided to take a conservative route rather than sounding an alarm to screen everyone. Much of the cost saved, she said, is not necessarily in prevention of ESRD but in preventing deaths. Also, reviewers and editors of journals are skeptical and cautious about how findings are reported so the investigators had to strike a balance in their views. Dr. Boulware also explained rationale behind assumptions made in the study.

Committee members suggested some follow-up activities pertaining to the paper:

- They asked Dr. Boulware to provide references for the cost-effectiveness of proteinuria screening compared to other chronic conditions. That information is important to bring home the idea that CKD and renal disease have sufficient burden like cancer.
- NKDEP could take this paper to the U.S. Health Service Task Force and ask them to reconsider their decision to not do protein screening in the U.S. population.
- Supplement the cost effectiveness message with a table showing the burden of disease, i.e. a life table showing the cumulative risk of developing CKD compared to types of cancers, for example, and show those who end up with ESRD by age group (usually ages 50 and greater). This would show that screening is cost effective and saves lives as well as illustrating the burden of disease.
- Consider incorporating risk of CVD events (the model used CVD deaths) into the model. That could improve the cost effectiveness of screening.

Anton Schoolwerth, MD, MSHA
Centers for Disease Control and Prevention

Dr. Schoolwerth presented an overview of the Centers for Disease Control and Prevention (CDC) efforts towards a CKD National Public Health Action Plan that he helped develop during a year's sabbatical spent there. The CDC does not have a division devoted to kidney disease; it is found only as a complication of diabetes. Dr. Schoolwerth worked on a plan to increase awareness of CKD at the CDC and bring it more to the forefront of activities there.

Dr. Schoolwerth said the CDC considers something a public health problem when it meets three criteria: 1) There is a high disease burden, 2) rapid changes occur in that burden going from low to high and 3) there is a sense of fear. CKD fits all three of these criteria. It disproportionately affects the elderly, minorities and the disadvantaged. KD currently ranks number 9 among the leading causes of death. The data, however, are gleaned from death certificates so the number would be higher if there were a better way to ascertain the prevalence of kidney disease.

The CDC wants to work with NKDEP. They are talking about doing education through NKDEP while they supply surveillance, epidemiology and outcomes data. There is an unfunded mandate from Congress that the CDC become involved in kidney disease. The CDC needs a strategy to combat CKD and funding. Dr. Schoolwerth and colleagues developed a White Paper for Congress to elicit funds for the following:

- Sponsor a Consensus Conference with the NKF to develop a Public Health Kidney Disease Action Plan
- Develop capacity at the CDC for CKD surveillance, epidemiology and outcomes program
- Set up pilot programs in 3-5 states for CKD prevention, detection and treatment.

Dr. Schoolwerth closed his presentation saying that the CDC wants to collaborate with NKDEP in the development of a Public Health Kidney Disease Action Plan. They would like to use the CDC strengths to leverage the goals of NKDEP.

Partnership Contributions to the NKDEP Effort
See Appendix 1

IV. NKDEP STRATEGIC PLAN
Thomas Hostetter, MD

Dr. Hostetter reviewed key points in the strategic plan formulated 3 years ago and the status of each item. He emphasized the importance of partnerships. Some of the things NKDEP has done in the field have been accomplished due to partnering with outside organizations. Key items in the plan and their status are as follows:

- Guidelines
  The plan lists reviewing, supporting, disseminating and guidelines. NKDEP has chosen not to write guidelines especially since some important ones have been written such as KDOQI and JNC VII (7th report of the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure). They have assisted in promulgating these guidelines and sponsored a meeting with NKF on proteinuria that resulted in a consensus statement.
- Tools
  NKDEP has done much work in this area
- Develop awareness
  NKDEP has targeted several audiences in whom they have worked to raise awareness of CKD and its serious nature. A new audience to target is dialysis patients and their families. They have used a variety of media to accomplish this goal.
- Personal Risk Factor Assessment
  NKDEP has fact sheets for African Americans at risk. The GFR explanation sheet will be sent when a doctor sends a patient laboratory results.

- Whole Spectrum of CKD
  NKDEP has not worked on the "whole spectrum." They emphasized pre-symptomatic CKD and the need for testing rather than planning for dialysis, bone care, etc.
- Use Various Media
  NKDEP has utilized various media.
- Promote Activities That Improve Quality and Access to Care
  NKDEP has not written White Papers for policy makers. They have worked on laboratory reporting of GFR estimates.
- Coding Billing and Reimbursements
  NKDEP has a MOU with CMS on this. They also have a fact sheet on how coding should be done.
- Reduce Errors
  The Consult Letter Template was a project, which will ultimately help reduce errors. They are working on a standardized creatinine assays for laboratories across the country.
- Performance Measures
  NKDEP partnered with CMS on a pilot in CVD.

Other areas NKDEP might address in the future include:

- Address Other Target Audiences
  Other target audiences include the elderly who might benefit from screening and other ethnic groups.
- Policy Papers
  NKDEP has not put out Policy Papers. Perhaps one on a cost effectiveness analysis would be useful? Should NKDEP put out a White Paper on the value of testing, therapy, etc.?
- Albuminuria
  The albuminuria testing is not standardized either. Should NKDEP work on this?
- Dissemination Channels
  This is a challenge. Ideas on dissemination are welcome.
- Interaction with Non-Profits and Government and Industry
- Engaging PCP
  This is hard to do and better ways to reach PCPs are also welcome
- Evaluation Project
  NKDEP will have to apply for another grant to do more evaluation. Should NKDEP evaluate how many laboratories implement estimated GFR reporting? What are the consequences of doing or not doing evaluation?

Dr. Hostetter said these were the major points from the Strategic Plan. He asked participants to break out into groups to brainstorm ideas for the NKDEP Strategic Plan for 2004 and then present their discussion points to the full committee. To help focus the effort, Dr. Hostetter asked them to think about the following:

1. Review, support and disseminate science-based kidney disease care guidelines.
2. Develop, implement and disseminate KD awareness and education activities, materials and resources.

3. Promote policies and activities to improve quality and access to care.
4. Define new aspects of the NIH research agenda.
5. Evaluation.
6. Prioritization.

V. RECOMMENDATIONS

REVIEW, SUPPORT, DISSEMINATE SCIENCE-BASED KD CARE GUIDELINES
1. Endorse existing guidelines, e.g. NKF, RPA
2. Collaborate and co-brand guidelines; NKDEP should not develop its own guidelines. Go to organizations, societies with joint issues and put renal issues in their guidelines e.g. American Diabetes Association on issue of diabetic nephropathy. Emphasize harmonizing guidelines to facilitate co-branding, e.g. harmonization of RPA and KDOQI. Find colleagues in other organizations to help with the harmonization effort. Related to this, work with others to get CKD into their guidelines.
3. Make sure PCP organizations adopt and publish guidelines.
4. White Paper on performance measures based on CKD guidelines.
5. Work to have JCAHO adopt QI measures.
6. NKDEP should function as a central repository for existing guidelines on its Web site with links. Have an area on NKDEP Web site with 4-5 *Must Dos* from each of the key set of guidelines for busy PCPs.

DEVELOP, IMPLEMENT AND DISSEMINATE KD AWARENESS AND EDUCATION ACTIVITIES, MATERIALS AND RESOURCES
1. Expand target audiences, i.e. elderly, Hispanics, cardiologists, endocrinologists, community health centers, adolescents with rising Type II diabetes, obese, nurses working with high risk populations, critical care doctors, ER doctors, geriatricians while continuing to target African Americans, PCPs. Make sure audiences know this is a multi-ethnic disease.
2. Promote utilization of consultation letter and RPA packet available soon.
3. Partner with other subspecialty organizations.
4. Do secondary and tertiary messages, not primary.
5. Target certain states and their state health departments for pilot studies like those with high density of at risk patients in an area. Collaborate with National Association of Community Health Centers and state Chronic Disease Directors (CDD).
6. Put CKD in VA performance measures.
7. Get into medical school curriculum, perhaps in the 3rd year competency-based curriculum.
8. Use idea of “hang time” for GFR-- “hanging in there.” Use a celebrity to publicize the message.
9. Channels: Get reciprocal help from similar organizations like nurse practitioners and

physician assistants.
10. See if NKDEP can do a pilot program with a pharmacy chain to distribute NKDEP message with a kiosk or marketing materials in the bag with the pharmacy purchase.
11. Involve medical students to address competency issues.

PROMOTE POLICIES AND ACTIVITIES TO IMPROVE QUALITY AND ACCESS TO CARE
1. Engage Black Caucus.
2. Sponsor research on cost-effectiveness of early identification and intervention in CKD—key for policy makers.
3. Get universal adoption of GFR—make it mandatory for outlying labs, not just hospital labs.
4. Lobby for a CKD registry to get data and see if we are making changes in care.
5. NKDEP should highlight funding problems in transition from child to adult medical care and in changing jobs and getting medical coverage.
6. Work with individual organizations and have them lobby Congress with the CKD message.
7. Develop a business case for CKD rather than for ESRD; not necessarily saying that it is cost effective to identify people early and put people on drugs but better QOL and work productivity.
8. Do a CKD case study for improved quality of care leads to decrease in disparities.
9. Encourage organizations to revisit portions of their guidelines earlier than intended as new information becomes available.
10. Translate the messages, at least into Spanish.
11. Develop an appropriate construct emphasizing the economic benefits of early intervention.

DEFINE NEW ASPECTS OF THE NIH RESEARCH AGENDA
1. Encourage research on guidelines such as when/how to identify those with CKD, tools to use in screening, frequency of screening.
2. Encourage research to identify education materials to promote long-term change.
3. Need evidence to say materials are being used and make a difference.

EVALUATION
1. Evaluate consult letter template: Will nephrologists and PCPs like it? Will it make a difference in patient care?
2. Evaluate other guidelines we use.
3. Laboratory working group paper may change practice. Follow-up on it perhaps through CAP, or poll labs pre and post implementation. Need to change actual practice.
4. Evaluate whether or not NKDEP campaigns are working. Figure out how to teach the

message through repository, implementation of guidelines.
5. Evaluate lab reporting and its impact on provider.

PRIORITIZATION
1. Make sure current efforts mature and are utilized, e.g. lab effort, education initiative, consult letter template.
2. Insurance: who pays is important.
3. Simplify. Maintain simple message. Don't expand too much.
4. Take advantage of others' work and piggyback on it.
5. Repetition is important.
6. Take small steps forward.

VI. CONCLUSION

Dr. Hostetter thanked all for their participation. He summarized key ideas presented as follows:

- NKDEP should perform a catalytic role.
- Keep the message simple.
- Be a "pulpit."

Dr. Hostetter asked committee members to keep up active communication with NKDEP. He appreciates their ideas and feedback and does not want NKDEP to duplicate the efforts of their organizations. NKDEP, as part of NIH and as a federal organization, has a neutrality stance that can be beneficial. He will seriously consider today's recommendations for the next contractual phase of support.

VII. APPENDIX 1
Contributions of Steering Committee Organizations

American Heart Association (AHA)-Eric Simon, MD
Dr. Simon summarized key points from his earlier presentation on the activities of the Kidney Council of the American Heart Association pertinent to NKDEP. For AHA, the message is that kidney disease is a risk factor for CVD. AHA would like to work with NKDEP particularly with co-branding. This is a very large organization and their visibility as well as their lobbying expertise could be very helpful to NKDEP.

American Society of Hypertension-Domenic Sica, MD
The American Society of Hypertension (ASH) published an article in the *American Journal of Hypertension* on the past, present and future for NKDEP. They have a hyperlink on their Web site to NKDEP. They are going to survey 2500 members, 900 of whom are hypertension specialists, to create more recognition of CKD. The heads of the 7 individual U.S. Chapters will hear a presentation in January 2005 on strategies to implement education on kidney disease asking them to use local resources to implement NKDEP efforts. The Journal of Clinical Hypertension has donated space for periodic displays of developments in NKDEP. That publication goes to 50,000 people. They also offered to share their booths at conferences and meetings with NKDEP.

Laboratory Working Group-John Eckfeldt, MD, PhD
Dr. Eckfeldt summarized the work of the Laboratory Working Group on standardizing creatinine assays and implementing reporting of estimated GFR using the MDRD equation. The group is comprised of representatives from industry, government and professional societies. The College of American Pathology is also interested in this effort. Dr. Eckfeldt welcomed ideas on how to support this campaign.

Veterans Health Administration-Thakor G. Patel, MD
Dr. Patel said the VA implemented reporting of estimated GFR system-wide in August 2004. They have 800 clinics. When a physician in the system orders a serum creatinine the result comes with an estimated GFR using the MDRD equation. The VA also has 10,000 residents that go through the system and thousands of medical students and 105 medical school affiliations. Dr. Patel said the VA could have a “huge impact.” Their Web site at http://www.va.gov/kidney is linked to NKDEP. The VA is also revising their guidelines based on the KDOQI recommendations.

American Academy of Family Physicians-Cynda Johnson, MD, MBA
Dr. Johnson works to educate PCPs on KD and the guidelines. She is Dean of the Brody School of Medicine at East Carolina University and also speaks in other countries on KD. She recently had an editorial published in the *American Family Physician* journal, on the KDOQI guidelines from the point of view of a PCP. Dr. Johnson said this publication normally does not publish guidelines from other groups. She is pleased to be a part of the effort to make changes in the care of those with CKD.

The Links, Inc.-Victoria Dent
Ms. Dent said her organization's activities fit well with those of NKDEP. The Links works to reach those in the community through their 10,000 members who are professional African American women (doctors, nurses, etc.) and through their affiliations with other organizations such as a pharmaceutical company and churches. This year The Links, Inc. will focus on African American transplant surgeons. They will use NKDEP materials. Ms. Dent's organization has 274 chapters in 42 states and 3 countries.

Indian Health Service-Andrew Narva, MD
Dr. Narva is Chief, Clinical Consultant for Nephrology and Internal Medicine with the Kidney Disease Program in the Indian Health Service (IHS) which takes care of 1.5 million people. He said they are trying to be "cutting edge" in improving the care of those with CKD. The population he serves has the highest risk for CKD in the U.S. Dr. Narva said the Indian Health Service does community-based work from screening at home to acute care in the hospital. This is a public health problem and they use a public health approach. Seventy-five percent of the diabetics cared for by the IHS are on ACE inhibitors. The IHS collaborates with all in improving care for American Indian people with CKD.

American Dietetic Association-Karen Basinger, MS, LN
Ms Basinger is from the Renal Practice Group of the American Dietetic Association (ADA). She is a renal dietician. She said her organization recently sent out guidelines for those with CKD. There is a link to NKDEP on the ADA Web site and they continue to work together. The ADA has several members in the four NKDEP pilot sites.

American College of Physicians
Joseph Kuhn, MD, FACP representing the American College of Physicians (ACP) said there are over 100,000 practitioners of internal medicine in the organization, which is "large and slow moving." The role of the College is mainly educational. They are interested in co-branding with NKDEP. They have a large national meeting annually and two chapter meetings locally each year. Dr. Kuhn speaks in Delaware on the management of kidney disease and anemia. He will get more nephrologists to speak in their local communities.

Derrick Latos, MD, MACP, also from ACP, is in private practice and teaches and does administrative work. The challenge with the ACP, he said, is how to get those at the highest level of decision-making involved in making CKD a high priority. In the past year, the ACP passed a resolution to identify those chronic diseases that have actionable programs and plans and to have the ACP work with organizations that have strategies to work on these diseases. The committees in the ACP, however, used diseases from the Institute of Medicine (IOM) and CDC reports and KD is not listed in those. The ACP will support NKDEP efforts towards a public health initiative on CKD. The ACP also has an educational program called Physicians' Interactive Education Resource or PIER, which has links to well written programs for every disease state. Dr. Latos said the ACP is

writing on CKD for PIER and a link to NKDEP would be good. Doctors can work in their offices and link to NKDEP to do the estimated GFR.

National Kidney Foundation-Anton Schoolwerth, MD, MSHA; Wendy Weinstock Brown, MD, MPH

Wendy Weinstock Brown, MD, is head of the Kidney Learning Centers for the National Kidney Foundation (NKF) and has written a paper on the tool kit. Their newsletter, *Best Practices*, will highlight the best practices in KD care. This goes to dialysis units. The NKF Web site also has short vignettes on a variety of topics related to the care of CKD patients.

Dr. Brown said the tool kit mentioned by Dr. Schoolwerth will be available at the American Society of Nephrology (ASN) meeting at the end of October in the exhibit hall. It includes materials for office administration staff and for physicians' waiting rooms. Dr. Brown thanked others present for their NKF Kidney Early Evaluation Program (KEEP) involvement. This effort is increasing the number of persons reached by 1600 per month and a paper will be published soon on the demographics of this population.

Juvenile Diabetes Research Foundation International-Shelley Lowenstein

Ms. Lowenstein said her organization is interested in changing the dynamics of the complications of diabetes, especially KD, and they would like to do early interventions. They can support NKDEP indirectly by putting NKDEP materials on their Web site and sending out NKDEP information. The Foundation also welcomes grant proposals for Type I diabetes related research. They have reviewed grant proposals on KD.

Polycystic Kidney Disease Foundation-Dan Larson, BS

Mr. Larson said a clinical trial of a drug to slow or stop the progression of polycystic kidney disease would soon be launched in Florida. Trials in Europe and Japan will begin in 2005. The drug looks promising in this indication and if it proves beneficial it will be a net gain towards lowering the incidence of CKD and ESRD.

Chi Eta Phi Sorority, Inc. –Carolyn Mosley, PhD, RN, CNS

Dr. Mosely said her role on the Steering Committee is to take the message to the community. Her organization is a community-based organization. She said those most at risk are those with no access to care. Her organization gives NKDEP educational materials to the community and does screenings, which people would not normally receive. The communities recognize and trust her organization and come out for events sponsored by it.

Society of General Internal Medicine-Neil Powe, MD, MPH, MBA

Dr. Powe said his organization, the Society of General Internal Medicine, is a cousin of the American College of Physicians. It is a smaller society of academic general internists. Its members (a few thousand physicians), teach in academic medical centers and have ACP memberships, too. Dr. Powe has been working to get CKD as a topic for the annual meeting. His organization offers courses prior to the meeting to update teachers of internal medicine on current topics and they want to offer one on CKD.

Association of Clinicians for the Underserved-Maggie Hobbs, MSW
Ms. Hobbs said kidney disease and diabetes are big problems among the underserved. Means must be found for the Association of Clinicians for the Underserved (ACU) to connect with organizations such as NKDEP. Her organization does spread the message to those working in the community. She hopes that the ACU can work with NKDEP as they do with the NKF.

American Kidney Fund-Forest Daniels, FACHE
Mr. Daniels is the National Director of Minority Intervention and Kidney Education for the American Kidney Fund (AKF). Their purpose is to get the message to the community. They provide services, follow-up care and education to the community. Those with proteinuria or a GFR less than 60 are called and told to see a doctor. Letters are also sent to those patients. They are holding workshops on KD for individuals and their families at the end of October and in November of this year. The AKF works with NKDEP. They collaborate via co-branding and sending a letter out signed by Dr. Hostetter and others for those at high risk to educate their doctors on the proper treatment of kidney disease. The AKF will post their findings on this effort at the end of this year. Mr. Daniels also presents information from NKDEP at different meetings such as that of the State Primary Care Association. This Association said they need materials on CKD.

Phylis Ermann from AKF said her organization has initiatives on CKD and publishes a booklet for patients on how to slow the progression of the disease. They did a mass mailing of it to PCP and endocrinologists' offices but were disappointed in the response. Their goal is to work with medical societies to get the materials to those who need them. They also do a series of dinner meetings on CKD for doctors. Staff of the AKF have been involved in the NKDEP pilot sites in Atlanta and Baltimore. They collaborated with the ACU and NKDEP on a quick reference card for members.

American Nephrology Nurses Association-Ann Compton, MSN, FNP-C
Ms. Compton functions as a liaison between the American Nephrology Nurses Association (ANNA) and NKDEP. She asked her organization for a CKD special interest group three years ago and she proudly reported that such a group started one month ago. They are working on a Stage 3 and 4 Action Plan for nurses. They are soon going to publish standards of clinical practice with the KDOQI guidelines integrated in them. Ninety percent of the members of ANNA do hemodialysis; those nurses are key targets now to get family members in for screening. Proper care means the patients have their blood pressure under control and anemia managed and they know about their disease state.

Centers for Disease Control and Prevention (CDC)-Kris Ernst, BSN, RN, CDE
Ms. Ernst is both a registered nurse and a diabetes educator in the Division of Diabetes Translation at the CDC. They sent NKDEP educational materials to all the state diabetes control programs. The Diabetes Control Programs must show work related to 7 national objectives. The CDC may add microalbumin screening and cardiovascular assessments to

the screenings for which they are responsible in this program. The state of Michigan has already added a CKD question to their diabetes module in their state questions.

Ms. Ernst said she is the past President of the American Association of Diabetes Educators and they, like the Nephrology Nurses, may add a special practice group for CKD. She herself has undergone a kidney/pancreas transplant and is a champion of early detection. She has written on diabetic nephropathy.

Agency for Healthcare Research and Quality (AHRQ)-Yen-Pin Chiang, PhD
Dr. Chiang is the Acting Associate Director of AHRQ, which is an interface between healthcare research and health research. They are now partnering with CMS to capture Quality Improvement from the patient perspective. This is downstream—once the patient is already in the system getting care. They are also developing a survey for use in dialysis facilities to ascertain the experience of care delivery and to capture the qualities of care and its outcomes. The goal is to provide a linkage between performance and payment and quality.

American Society of Pediatric Nephrology-Barbara Fivush, MD and Frederick Kaskel, MD
Dr. Fivush is Director of Pediatric Nephrology at Johns Hopkins University and Dr. Kaskel is a Professor of Pediatrics and Chief of Pediatric Nephrology at Children's Hospital at Montefiore. The ASPN works with NKDEP to target high-risk populations and wants to add pediatrics to the NKDEP mission. They want to have children in the community screened for KD. They do programs now in blood pressure and in identifying new guidelines to prevent target organ damage in kids. They also do Body Mass Index (BMI) calculations since there is an epidemic of obesity in the U.S. Thirty percent of children and adolescents are overweight, ten percent morbidly so. There is obesity-related microalbuminuria in this population. The Society developed a template of a letter modified from the current Renal Physicians Association (RPA) template. It is designed for doctors taking care of children. The ASPN wants to work with NKDEP.

American Academy of Physicians Assistants (AAPA)-Bob McNellis, MPH, PA-C
Mr. McNellis works closely with the NKF and as an organization the AAPA promotes the NKDEP messages in their newsletter (circulation 37,000) and to their Board of Directors. One member of the Board is also a Physician Assistant Program Director who makes her students participate in the KEEP program. They had 3 lectures on CKD this past year and reached 8000 Physician Assistants (PAs). Twice a year Mr. McNellis teaches a board review course in which he features NKDEP materials. PAs have to recertify every 3 years. There are CKD questions on that exam. The Academy has various on-going activities with NKDEP and will continue working with them.

American Society of Nephrology (ASN)-William McClellan, MD, MPH
Dr. McClellan partners with NKDEP in a CMS academic medical center quality improvement project. The ASN annual meeting will have a presentation this year on CKD in the session on health services outcomes. The CKD Advisory Committee wants to expand the program educational content on CKD for the 2005 meeting. The *Journal of*

the American Society of Nephrology has expanded the epidemiological outcomes and health services research content. They are also launching a new clinical journal with original research and medical/educational content on clinical nephrology and CKD.

American Academy of Nurse Practitioners—Mary Jo Goolsby, EdD, MSN, NP-C
Dr. Goolsby said the AANP has 85,000 members, 1000 of whom are nephrology nurse practitioners. They are developing awareness on CKD via such things as their journal which had a review of the KDOQI guidelines, presentations at their national conference on CKD and free booth space given to NKDEP and NKF at their meetings. They also highlight their activities with NKDEP in their newsletter.

Renal Physicians Association-Richard Goldman, MD
Dr. Goldman is Chair of the Quality and Accountability Committee of the Renal Physicians Association (RPA). Dr. Goldman said the RPA is interested in partnering with NKDEP to develop tools to implement guidelines and to improve CKD care. The RPA saw 5 years ago that there would be a shortage of nephrologists so collaboration with PCPs is needed in order to give high quality care for CKD. Point of care tools are needed to facilitate that effort. RPA also wants to develop performance measures on a spectrum from quality improvement to payment performance.

Forum of ESRD Networks-Derrick Latos, MD, MACP
Dr. Latos is Vice President of the Board of Directors of the Forum of ESRD Networks. They want to develop valid and fair performance measures. Performance measures are essential, Dr. Latos said, to improve quality and need to valid and fair. He pledged to work with NKDEP on these measures.

National Kidney and Urologic Diseases Information Clearinghouse (NIDDK)-Dan Garver
Mr. Garver is a health writer for the National Clearinghouse and he is also a patient. The Clearinghouse has a toll free number for patients to get information as well as a database of health information. The focus is on patient materials in the database. Mr. Garver develops fact sheets and booklets for patients and works closely with NKDEP.

NephCure Foundation-Henry Brehm
Mr. Brehm said the mission of NephCure Foundation is to raise awareness for FSGS research. The Foundation sent out NKDEP materials to all chapters and is interested in marketing and PR efforts in collaboration with NKDEP. They want to reach people early in the disease process and get them screened so educational materials are important in achieving this goal.